K003004

OCT 2 5 2000

SunTech Medical Instruments Inc.
Special 510(k) Submission
Oscar 2 Automatic Blood Pressure Measurement System
510(k) Summary

(1) Submitter information

Name :	SunTech Medical Instruments Inc.
Address:	8917 Glenwood Ave. Raleigh, North Carolina 27612
Telephone:	1 919 782 3005
Contact person:	David Gallick (Official Correspondent). SunTech Medical Instruments Inc. 8917 Glenwood Ave. Raleigh, North Carolina 27612 1 919 782 3005
Date prepared :	September 22, 2000

(2) Name of Device

Trade Name:	Oscar 2 Automatic Blood Pressure Measurement System
Common Name:	Automated Blood Pressure Monitor
Classification name:	System, measurement, blood pressure, non-invasive, systolic and/or diastolic, 74JOE, 870.1130

(3) Legally-marketed predicate devices

Accutracker DX, K913844B, also made by SunTech Medical Instruments.

Omega 5600, K 945138, Invivo Research

The Oscar 2 is substantially equivalent to these devices.

(4) Description

The Oscar 2, a microprocessor based ambulatory blood pressure monitor, uses an oscillometric step deflate technique to determine blood pressure. An internal electric

pump is used to inflate the cuff, and deflation is controlled by two valves. During cuff deflation, small cuff pressure changes (resulting from arterial blood pressure pulses) are analyzed by the microprocessor, in order to determine the blood pressure. Oscar 2 has the ability to make blood pressure measurements at predetermined intervals (normally from a schedule determined by the physician), or on demand (by using the stop/start key). Each reading is stored in memory, allowing the physician to download all the results obtained during the study period after the study has concluded, to be analyzed by the PC software. The readings can be displayed on the LCD or the LCD display can be disabled to prevent the patient from seeing the readings.

The associated AccuWin Pro PC-based program provides the setup, display and record-keeping functions of the system. A measurement schedule can be constructed with the AccuWin Pro program, and then up-loaded into the Oscar 2 monitor. Once the schedule is loaded in the OSCAR 2 unit the OSCAR 2 system is put on the patient at the physician's office or clinic. The patient then wears the monitor for the duration of the study (usually 24 hours.) After the ambulatory blood pressure (ABP) study has been completed, the stored readings in the Oscar 2 are downloaded to a PC using the AccuWin Pro program. The AccuWin Pro program provides the data in tabular and graphic form, as well as a patient report.

(5) Intended Use

The Oscar 2 system is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to be used with AccuWin Pro, a PC-based computer program for the recording and displaying of up to 250 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult patient's systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display. It makes no diagnoses.

(6) Performance Data

(a) Non-clinical tests

The Oscar 2 has passed the following tests f or electrical safety:

- IEC 601-1 for Electrical Safety
  IEC 601-1-2 for Electromagnetic Compatibility
  IEC 602-2-30 Electrical Safety and Performance

The Oscar 2 has passed all of the tests required in AAMI SP10, automated sphygnomanometers.

(a) Clinical tests

Since the Oscar 2 uses the same technology as existing devices, clinical tests are not required. However, to satisfy SP10, the system is compared with manual readings on patients, and it has satisfactorily passed this test.

(7) Conclusion

The Oscar 2 Automated Blood Pressure Monitor system is equivalent in safety and efficacy to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2000

Mr. David Gallick
Official Correspondent
SunTech Medical Instruments Inc.
8917 Glenwood Ave.
Raleigh, NC 27612

Re: K003004
Trade Name: Oscar 2 Automatic Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: September 21, 2000
Received: September 26, 2000

Dear Mr. Gallick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K003004

Indications for Use Form

Device Name: Oscar 2 Ambulatory Blood Pressure Measurement System

Indications for Use:

Oscar 2 is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to be used with AccuWin Pro, a PC-based computer program. The OSCAR 2 is capable of recording and displaying up to 250 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult patient's systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display. It makes no diagnoses.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ **OR** **Over-the-Counter Use**_____
(Per 21 CFR 810.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K003004